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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,221	03/07/2001	Paul Sanberg	C14-135	5403

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)
	09/801,221	SANBERG ET AL.
	Examiner	Art Unit
	Anne-Marie Falk, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *21-42 and 62-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 43-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

☒ Notice of References Cited (PTO-892)
☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7, 8, 9* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The response filed September 5, 2002 (Paper No. 13) has been entered.

Claims 1-69 are pending in the instant application.

Claims 21-42 and 62-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 13.

Accordingly, Claims 1-20 and 43-61 are examined herein.

Drawings

The drawings are objected to. See the attached Notice of Draftsperson's Patent Drawing Review (PTO-948). Applicant may not request that any objection to the drawings be held in abeyance. See 37 CFR 1.85(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 43-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to neural cells, a method of producing neural cells, and cell compositions.

The specification fails to provide an enabling disclosure for the claimed compositions and methods of making said compositions because methods of transplantation of neural tissue or other cells into the CNS or PNS are not routinely successful and the specification does not offer adequate guidance

to enable one skilled in the art to practice the claimed invention to derive a therapeutic benefit in a diseased animal. The specification teaches that the only use for the claimed compositions is for transplantation to produce a therapeutic effect but the specification does not adequately teach how to use the claimed method to produce such an effect. Jackowski et al. (1995) details the limitations and unpredictability associated with the transplantation of neural tissue. At page 311, column 1, paragraph 2, the reference discusses the barriers to successful transplantation of neural tissue, notably the presence of molecules that actively inhibit the regeneration of mammalian CNS and PNS axons. The specification does not offer any guidance as to how the claimed compositions could be used therapeutically for the treatment of any disorder, including Parkinson's disease (PD), Alzheimer's disease (AD), Huntington's disease, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), Tay Sach's disease, Rett Syndrome, lysosomal storage disease, ischemia, spinal cord damage, ataxia, schizophrenia, or autism, as contemplated in the specification. No working examples demonstrate a therapeutic effect upon transplantation of the claimed compositions. The specification provides general teachings only (see pages 1-8 of specification), but does not provide specific guidance for treating a pathological condition. The specification fails to provide any guidance relating to the number of cells to inject, the site of injection, and the extent of cellular persistence required and attainable in practice, to provide any therapeutic benefit for the treatment of any disorder.

Given the lack of specific guidance in the specification, the broad scope of the claims, and the lack of working examples directed to therapeutic transplantation of the compositions, one of skill in the art would have been required to engage in undue experimentation to make and use the claimed compositions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-7, 8-14, 17-20, and 43-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 5, 7, 8-10, 13, 14, and 19 are indefinite in their recitation of "silencers" because the metes and bounds of the term are not clearly set forth.

Claims 2, 5, 7, 8-10, 13, 14, and 19 are indefinite in their recitation of "cell signalling molecules" because the metes and bounds of the term are not clearly set forth.

Claims 2, 5, 7, 8-10, 13, 14, and 19 are indefinite in their recitation of "neuroproteins" because the metes and bounds of the term are not clearly set forth.

Claims 4-7 are indefinite in their recitation of "said stem or progenitor cells" because the phrase lacks antecedent basis.

Claims 11-14 and 17-19 are indefinite in their recitation of "pluripotent stem or progenitor cells within said mononuclear cells" because a cell cannot be located **within** another cell.

Claims 11-14 and 17-19 are indefinite in their recitation of "said sample of pluripotent stem or progenitor cells within said sample" because the phrase lacks antecedent basis and the second instance of "said sample" has ambiguous antecedent basis. Claim 11 refers to a "sample of mononuclear cells" but does not refer to a "sample of pluripotent stem or progenitor cells." Rather the claim refers to "pluripotent stem or progenitor cells within said mononuclear cells."

Claim 7 is indefinite in its recitation of "wherein said neuronal cells are selected from the group consisting of mesencephalic and striatal cells" because it is unclear if the claim is intended to be limited to methods of using mesencephalic or striatal cells as the differentiation agent. As written, Claim 7 still covers the use of retinoic acid, BDNF, GDNF, NGF, FGF, etc. as the differentiation agent.

Claim 14 is indefinite in its recitation of "wherein said neuronal cells are selected from the group consisting of mesencephalic and striatal cells" because it is unclear if the claim is intended to be limited to

methods of using mesencephalic or striatal cells as the differentiation agent. As written, Claim 14 still covers the use of retinoic acid, BDNF, GDNF, NGF, FGF, etc. as the differentiation agent.

Claim 17 is indefinite in its recitation of "said anti-proliferative cell agent" because the phrase lacks antecedent basis.

Claim 18 is indefinite in its recitaion of "said mitogen" because the phrase lacks antecedent basis.

Claim 20 is indefinite in its recitation of "said retinoic acid" because the term lacks antecedent basis.

Claim 43 is indefinite in its recitation of "effective amount" because it is unclear what the composition is "effective" for.

Claims 44-49 are indefinite in their recitation of "[t]he composition according to claim 40" because Claim 40 is directed to a method, not a composition. Accordingly, Claims 44-49 have not been further treated on the merits.

Claims 50-53 are indefinite in their recitation of "said umbilical cord blood" because the phrase lacks antecedent basis.

Claims 50-53 are indefinite in their recitation of "said stem or progenitor cells" because the phrase lacks antecedent basis.

Claim 53 is indefinite in its recitation of "said neuronal cells" because the phrase lacks antecedent basis.

Claims 54-56 are indefinite in their recitation of "combining said cells obtained from step b with a pharmaceutically acceptable carrier, additive or excipient" because the preamble recites "producing a pharmaceutical composition comprising neural cells" and step b is directed only to isolating a sample of pluripotent stem or progenitor cells and does not involve producing neural cells. Rather, step c involves the production of neural cells.

Claims 57-61 are indefinite in their recitation of "pluripotent stem or progenitor cells within said mononuclear cells" because a cell cannot be located **within** another cell.

Claims 57-61 are indefinite in their recitation of "said sample of pluripotent stem or progenitor cells within said sample" because the phrase lacks antecedent basis and the second instance of "said sample" has ambiguous antecedent basis. Claim 57 refers to a "sample of mononuclear cells" but does not refer to a "sample of pluripotent stem or progenitor cells." Rather the claim refers to "pluripotent stem or progenitor cells within said mononuclear cells."

Claims 57-61 are indefinite in their recitation of "said neural cells" because the phrase lacks antecedent basis. Claim 57 refers to changing the phenotype of a cell "to neural" but does not actually refer to the resulting cell as a "neural cell."

Claim 61 is indefinite in its recitation of "said neuronal cells" because the phrase lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kopen et al. (1999).

The claims are directed to neural cells.

Claims 1-3 are product-by-process claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product docs not depend on its method of production. See MPEP 2113. Thus, the claims read on neural cells

disclosed in the prior art, as discussed below. There are no structural limitations to distinguish the claimed cells from any other neural cell.

Kopen et al. (1999) disclose that marrow stromal cells (MSCs) injected into the lateral ventricle of neonatal mice differentiated into astrocytes and neurons.

Thus, the claimed compositions are disclosed in the prior art.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds et al. (1992).

The claims are directed to neural cells.

Claims 1-3 are product-by-process claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See MPEP 2113. Thus, the claims read on neural cells disclosed in the prior art, as discussed below. There are no structural limitations to distinguish the claimed cells from any other neural cell.

Reynolds et al. (1992) disclose neurons, astrocytes, and neuroepithelial stem cells. All three cell types qualify as "neural cells" as instantly claimed.

Thus, the claimed compositions are disclosed in the prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tiffiany Tabb, whose telephone number is (703) 305-1238.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE BAKER
PATENT EXAMINER